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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0438]

**Food Code Prohibition Against Bare Hand Contact With Ready-to-Eat Foods;
Preparation of a White Paper for Review by the National Advisory Committee on
Microbiological Criteria for Foods**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a request for scientific data and information to aid in the development of a white paper, or summary of current information, on the contamination of ready-to-eat foods associated with food preparation employees. FDA will present the white paper to the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) for its review and recommendations. FDA is seeking NACMCF input on this food contamination issue at the request of the Conference for Food Protection (CFP).

DATES: Submit data and information by *(insert date 60 days after date of publication in the Federal Register)*.

ADDRESSES: Submit written data and information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John J. Guzewich, Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-260-3847.

SUPPLEMENTARY INFORMATION:

I. Background

FDA provides assistance to local, State, and Federal governmental bodies to ensure that the food that is provided to consumers by retail food establishments is not a vehicle of communicable diseases. One mechanism for providing that assistance is the publication entitled *Food Code 1999* (1999 Food Code), which provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted by jurisdictions for regulating the retail segment of the food industry. The 1999 Food Code, which is published by FDA, is the cumulative result of the efforts and recommendations of many contributing individuals, agencies, and organizations, and it is developed under the auspices of the CFP.

The CFP, which is an organization of government, industry, consumer, and academic members, meets every 2 years to discuss retail food safety issues and to make recommendations on changes to be made to the 1999 Food Code. Delegates of State regulatory agencies vote on these recommendations that, if passed, are shared with organizations interested in amending or adopting the code. Recommendations with which FDA concurs are incorporated in the following year's edition of the Food Code.

In the 1998 CFP meeting, a number of issues were submitted for the CFP's consideration regarding section 3–301.11 of the 1999 Food Code, entitled “Preventing Contamination from Hands.” Section 3–301.11 states, in part, that “food employees may not contact exposed, ready-to-eat food with their bare hands.” The 1999 Food Code contains: A prohibition against ill or infected employees preparing food, a hand-washing regimen, and a blanket prohibition against bare hand contact with ready-to-eat foods in order to ensure that the person-to-food fecal-oral transmission cycle is broken.

Section 3–301.11 was added to the 1999 Food Code some years ago in response to outbreaks of food-borne illness caused by food that had been contaminated with pathogens transmitted by food preparation workers. Indeed, it is estimated that as many as one-third of the cases of food-borne illness can be attributed to contamination of food from food preparation workers. FDA

believes that the significant number of illnesses transmitted by worker contamination of food demand vigorous and rigorous intervention measures.

A number of the 1998 CFP issues opposed the current requirements in section 3–301.11 as too restrictive. In response, FDA proposed that the CFP defer consideration of many of the issues related to bare hand contact with ready-to-eat food and ask the NACMCF to review the issues and provide recommendations regarding unresolved scientific questions in time for FDA to report them to the 2000 CFP meeting. The delegates at the 1998 CFP meeting accepted the FDA recommendation.

II. Request for Data and Information

FDA is preparing for presentation of this issue to the NACMCF by developing a white paper, i.e., a summary of current information from scientific literature and other sources, that identifies and evaluates both the risks related to microbiological contamination of ready-to-eat food by food preparation workers and the effectiveness of different interventions to prevent or minimize that risk (e.g., hand washing, hand sanitizers, disposable gloves, no bare hand contact). In order to ensure that this white paper contains all available data relating to the risks and effectiveness of interventions to prevent or minimize contamination of ready-to-eat food, FDA is requesting scientific data, studies, or other information related to the following questions and issues:

1. FDA seeks scientific data or information on the risk of transmitting bacterial, viral, or parasitic pathogens from food preparation workers, via ready-to-eat food, to consumers, including scientific data and information relating to:

- a. The amount of hand contact that can result in the transfer of pathogens;
- b. Whether transient contact, such as might occur when placing a garnish on a plate or glass, can transfer pathogens;
- c. Whether pathogens can be transferred to raw produce while washing it, if bare hands are used; and
- d. Whether bare hands can transmit pathogens to dry food like toast or rolls.

2. FDA seeks scientific data or information on the effectiveness of alternative interventions, either alone or in combination, including scientific data and information relating to:

a. Hand washing with soap:

i. What constitutes a properly done hand wash;

- How long should the hand-washing process last;
- What is the optimum temperature of the water;
- Whether the use of a nailbrush increases removal of pathogens;
- Whether it is likely that a nailbrush would become a fomite, that is, become contaminated,

and transmit bloodborne or enteric pathogens to subsequent users;

- How long before subdermal pathogens recontaminate the skin's surface; and
- Whether hand-drying methods have an impact on microbial reduction.

ii. Whether a double hand wash is significantly better than a properly done single wash.

b. Hand-washing machines; whether the use of a hand-washing machine can be the “equivalent” to a properly done hand wash, and if so, under what conditions.

c. Use of “hand sanitizers:”

i. Whether human skin can be “sanitized;”

ii. Whether chemical hand sanitizers are effective against all pathogens of concern;

iii. Whether subdermal pathogens can recontaminate the skin and, if so, how long it would take; and

iv. Whether the use of hand sanitizers can increase the number of pathogens on hands.

d. Use of disposable gloves:

i. Whether pathogens can increase in numbers on gloved hands;

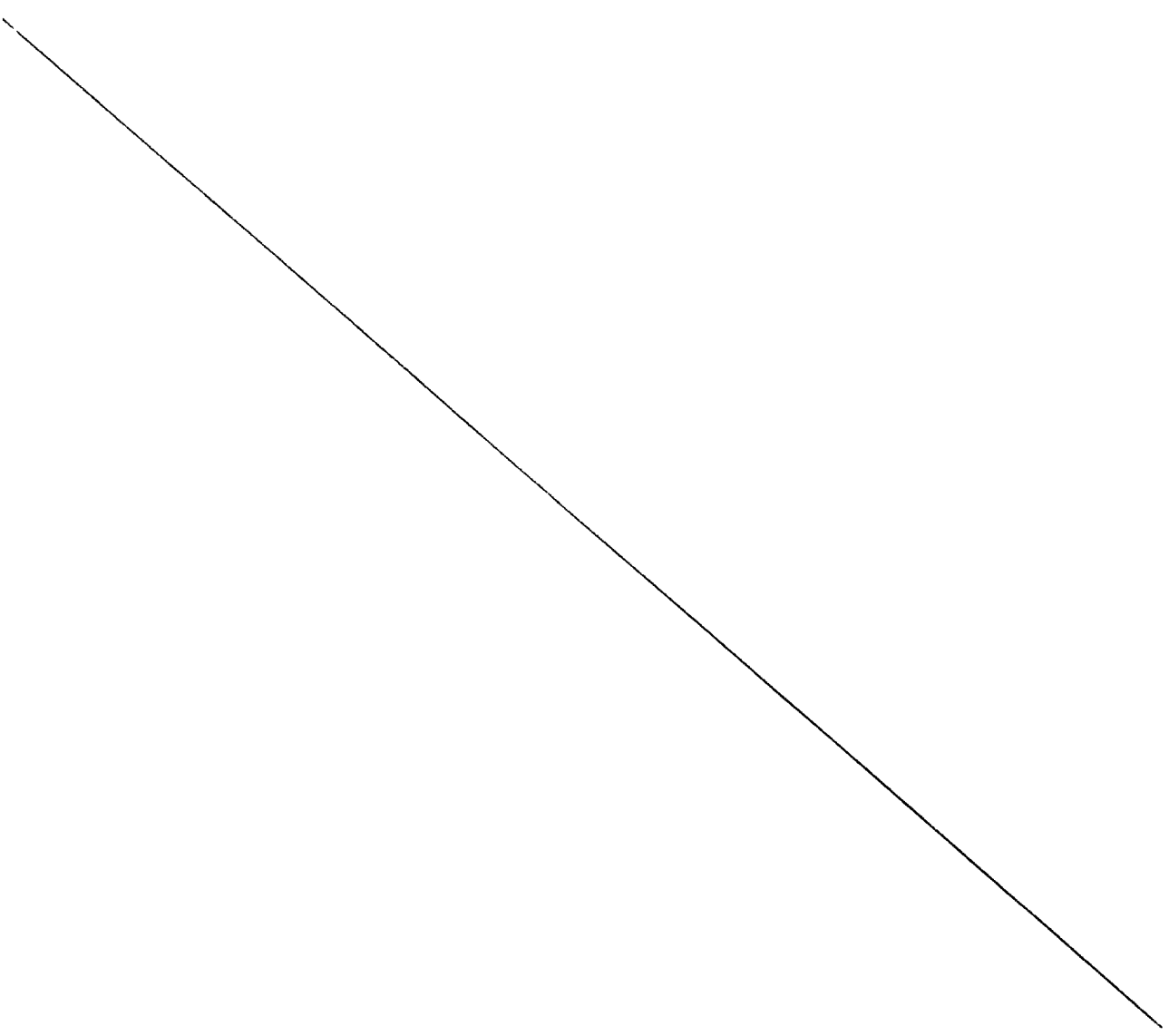
ii. Whether gloves are likely to become fomites themselves even when properly used, e.g., as they are being put on; and

iii. Whether glove use procedures used in other venues are applicable in retail food establishments.

e. Whether there are other interventions that should be considered to prevent or minimize microbial contamination of ready-to-eat food by food preparation employees.

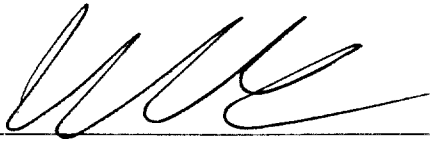
Finally, FDA is also interested in views on whether additional studies, either microbiological or epidemiological, are needed to fill existing knowledge gaps; and, if so, what kind of studies should be done.

Interested persons may, on or before *(insert date 60 days after date of publication in the Federal Register)*, submit to the Dockets Management Branch (address above) the required data and information. Two copies of the data and information should be submitted, except that individuals may submit one copy. Data and information are to be identified with the docket number



found in brackets in the heading of this document. Received data and information may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 25, 1999
March 25, 1999



William K. Hubbard
Acting Deputy Commissioner for
Policy

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